PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION [emblem]
International Bureau
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification [6]: **A61B 17/068, 17/072, A61M 37/00**	**A1**	**(11) International Publication Number:** **WO 99/26543** **(43) International Publication Date:** 3 June 1999 (03.06.99)

(21) International Application Number: ***PCT/EP98/07365***

(22) International Filing Date: 17 November 1998 (17.11.98)

(30) Priority Data:
197 51 791.9 22 November 1997 (22.11.97) DE

(71)(72) Applicant and Inventors: PIER, Arnold [DE/DE]; Anton-Schürkes-Strasse 9, D-52525 Heinsberg (DE).

(72) Inventors; and
(75) Inventors/Applicant *(for US only)*: HUMMEN, Jörg [DE/DE]; Mauerstrasse 21, D-52064 Aachen (DE).

(74) Agents: DALLMEYER, Georg et al.; Deichmannhaus am Dom, D-50667 Cologne (DE)

(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
with international search report.

(54) Title: [Original English title] SURGICAL CLIP APPLYING INSTRUMENT

(54) Title: [English Translation of German title] SURGICAL CLIP APPLYING INSTRUMENT

[image]

(57) Abstract

[Original English abstract. The original English abstract differs from the translation of the German abstract provided below.] The invention relates to a surgical clip applying instrument (1), comprising a handle (4) with an operating device (6), a shaft tube (2) which is attached to said handle (4) and in which a slide rod (28) is located and a clip device (10) at the distal end of the slide rod (28). Said slide rod (28) can be axially displaced with the operating device (6). According to the invention, the clip device (10) has a holding device (14) for a fluid port (15).

(57) Abstract

[English translation of German abstract] The invention relates to a surgical clip applying instrument (1), comprising a handle (4) with an actuating device (6), a shaft tube (2) that is attached to said handle (4) and in which a pushrod (28) is located that can be moved axially by the actuating device (6), and a clip device (10) at the distal end of the pushrod (28), with said clip device (10) having a receptacle (14) for a fluid port (15).

FOR INFORMATIONAL PURPOSES ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia-Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico		
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**UZ**	Uzbekistan
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**VN**	Vietnam
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**YU**	Yugoslavia
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand	**ZW**	Zimbabwe
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakhstan	**RO**	Romania		
CZ	Czech Republic	**LC**	St. Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

Surgical Clip Applying Instrument

The invention relates to a surgical clip applying instrument according to the preamble of claim 1.

Such a clip applying instrument is used to fasten a fluid port subcutaneously, e.g., on the abdominal musculature.

Fluid ports are necessary, for example, in connection with gastric bands that are looped around the stomach for the treatment of pathological obesity, in order to reduce stomach volume. A gastric band consists of a loop portion with a balloon element that can be expanded with fluid in order to reduce the diameter of the loop. The fluid is introduced under pressure from the fluid port through a flexible tube into the balloon element, thereby reducing the interior cross-section of the loop-shaped gastric band.

The fluid port is positioned close to the abdominal wall so that fluid can be added to or removed from the fluid port by transdermal injection, thereby allowing the size of the loop to be adjusted.

Known fluid ports are normally sutured to the abdominal musculature, with this suturing of the fluid port being quite time-consuming.

The aim of the invention is therefore to create a clip applying instrument that can be easily used to fasten fluid ports inside the body.

This aim is achieved by the features of claim 1.

The invention advantageously provides for the clip device to have a receptacle for a fluid port. Integrating the fluid port receptacle into a clip device has the advantage that the fluid port can be immediately brought into the proper position when the clip applying instrument makes contact and can be clipped to the surface of the body in a single operation.

The clip device is preferably comprised of a head piece that can be removed from the shaft tube. In this way, the head piece can be designed as a single-use disposable part, while the remaining parts of the clip applying instrument can be reused after sterilization.

The receptacle has a holding device for the fluid port. The holding device ensures that the fluid port is held

securely while the clips are pushed forward and cannot fall out of the instrument prematurely.

A number of fastening tabs are molded onto the fluid port, with the clips of the clip device and the fastening tabs being matched to each other. The fastening tabs are accordingly designed to receive the clips and allow the fluid port to be directly clipped to the surface of the body.

The fastening tabs have crosspieces for bending the clip legs of the clips. The crosspieces are spaced so that there is a gap between them and the clip legs.

The clip device has a clip pusher for each clip being attached that pushes the clip forward axially in the distal direction and uses two projections that work together with the crosspieces of the fastening tab to bend the clip legs of the clip. The projections engage at the outer edges of the clip at the height of the clip legs and cause the clip legs to bend such that the ends of the clip legs overlap.

The clip device has a plunger that can be moved axially by the pushrod. This plunger does not need to be connected to the pushrod, but is pushed forward in the distal direction by the pushrod.

An ejector for the fluid port is attached to the plunger, with the ejector positioned so that it is separated axially from the plunger.

The plunger exerts axial pressure against an actuating device for the clip pushers via a compression spring when the pushrod moves distally.

The compression spring is mounted on a rod part located between the plunger and the ejector.

The actuating device for the clip pushers is comprised of an annular washer that is mounted axially on the rod part extending axially from the plunger and pretensioned by the compression spring. The annular washer applies the pressure exerted by the compression spring equally to all of the clip pushers.

The annular washer, in its pretensioned resting position, bears against a stop formed by the ejector.

The receptacle for the fluid port accommodates both the clips for the fastening tabs and the clip pushers. Both are accommodated in matching cut-outs on the outer circumference of the receptacle.

The holding device is comprised of a number of holding springs that engage under an annular edge on the outer circumference of the fluid port. This annular edge is preferably formed by a metal shell on the fluid port.

The headpiece that can be removed from the shaft tube is comprised of a threaded head and a pipe section connected to the threaded head. The headpiece can be disposed of after being used, while the rest of the instrument is advantageously made reusable by sterilization. The

threaded head is, for example, connected to the shaft tube by a screw thread, while the pipe section is in turn connected to the threaded head by a screw thread.

The receptacle for the fluid port is integrated into the clip device and located at the distal end of the pipe section.

In a preferred embodiment, the pivoting lever part of the handle is positioned against a stop when in its resting position. An unlocking device can be used to release this stop in order to allow the pushrod to be removed from the proximal end of the shaft tube.

An embodiment of the invention is described in detail below with reference to the drawings.

The drawings show the following:

Fig. 1 The surgical clip applying instrument according to the invention
Fig. 2 A top view of the instrument shown in Fig. 1
Fig. 3 A cross-sectional view of the headpiece of the instrument
Fig. 4 A cross-sectional view along line IV-IV in Fig. 3
Fig. 5 Bending of the clip legs
Fig. 6 Ejection of the fluid port
Fig. 7 A side view of the fluid port
Fig. 8 A top view of the fluid port
Fig. 9 A cross-sectional view along line IX-IX in Fig. 8

Fig. 10 A cross-sectional view of the distal end of the headpiece

The clip applying instrument 1 is comprised of a shaft tube 2, that is rotatably mounted in a handle 4 and can be rotated around the longitudinal axis of shaft tube 2 using turning handle 16. Handle 4 is comprised of a pivoting lever part 6 and a fixed grip part 8, with pivoting lever part 6 acting via upper lever arm 7 on headpiece 26, which is located on the distal end of pushrod 28. Pushrod 28 has a guide element 24 at its proximal end, preferably made of plastic, that slides within the borehole of pipe-shaped shaft tube 2, where it centrally guides pushrod 28.

Shaft tube 2 is rotatably inserted in a pipe-shaped section of handle 4 that widens in a step-shape at the proximal end, forming a stop for the axial movement of pushrod 28. Guide element 24 with hemispherical headpiece 26 is axially guided within the widened portion of the cross-section. Compression spring 32 is positioned coaxially on guide element 24, between headpiece 26 and the proximal end of shaft tube 2, and bears against headpiece 26 at one end and against the proximal end face of shaft tube 2 in handle 4 at the other end. Compression spring 32 produces the return movement of pushrod 28 when the pivoting lever part 6 of handle 4 is pivoted back to its stop or resting position.

Another distal guide element 20 is located at the distal end of pushrod 28.

Turning handle 16 is used to rotate shaft tube 2 along with headpiece 12 around the longitudinal axis of the shaft tube. Base body 2 is secured axially in handle 4 by means of stud screw 46, which engages in annular channel 48 on the outer circumference of shaft tube 2 at its proximal end.

There is a stop device 9 on grip part 8 of handle 4 that forms a stop surface 11 for upper lever arm 7 of lever part 6. Upper lever arm 7 rests against stop surface 11 when lever part 6 is in its resting position. Pushbutton 22 can be used to move cushioning stop device 9 sideways, so that upper lever arm 7 can be rotated further in a clockwise direction using lever part 6, allowing the pushrod and its guide element 24 and expansion element 20 to be pulled out of the proximal end of handle 4. The inner parts of clip applying instrument 1 can be removed in this way for sterilization.

Headpiece 12 is screwed to the distal end of shaft tube 2 by means of threaded head 35. Threaded head 35 is in turn screwed to pipe section 36, which contains clip device 10 and a receptacle for fluid port 15.

Distal guide element 20 of pushrod 28 passes through a borehole in threaded head 35 and can move plunger 25 axially in the distal direction within headpiece 12. Plunger 25 is axially guided in pipe section 36 and is connected via rod part 27 to ejector 26 for fluid port 15. Ejector 26 provides a stop surface 31 for annular washer 30 which is mounted so that it can slide along rod part 27. Rod part 27 is inside of compression spring 29,

which bears proximally against plunger 25 and distally against annular washer 30. The annular washer is pretensioned against stop 31 in this way.

Annular washer 30 is used to push a number of clip pushers 21 that are arranged around the circumference of the pipe section forward in a distal direction in order to clip fluid port 15, which is being held in receptacle 14, into the surface of the body. The clip pushers are held by clip device 14, which has matching cut-outs. Each of the cut-outs holds a clip 18 and, located proximally from clip 18, a clip pusher 21.

Manipulating pivoting lever part 6 moves pushrod 28 forward in the distal direction, causing guide element 20 to act upon plunger 25, pushing it forward in the distal direction. Annular washer 30 is also pushed forward with plunger 25 until it contacts the clip pushers 21, causing the clips 18 to be initially pushed through the fastening tabs 17.

Receptacle 14 is firmly attached to pipe section 36. Axial channels 37 on the outer circumference of receptacle 14 contain flexible holding springs 33 that engage behind fluid port 15 on annular edge 34 and hold it in position during the clip application process.

Fig. 3 shows a dotted line indicating the position of clip pusher 21 before the clips 18 have been pushed in. In order to attach the clips to body tissue, headpiece 12 is placed against the surface of the body and, as shown in Fig. 5, lever part 6 is moved further in order to push clip pusher 21 further forward. Fastening tabs 17 have two inner crosspieces 19 that work together with the projections 42 of clip pusher 21 to bend the clip legs 23 in such a manner that the clip legs 23 overlap within the body tissue, thereby enabling the fluid port 15 to be firmly anchored to the muscle surface. After the clips have been attached, further movement of lever part 6 causes ejector 26 to make contact with the fluid port, causing it to be ejected from head part 12. Holding springs 33 are bent apart and possibly deformed during the process.

The fluid port 15 shown in Fig. 7 and 8 has a preferably cylindrical chamber 50 with an opening on one side that is closed by a self-sealing silicon plug 54. Silicon plug 54 is enclosed within a metal shell 66 that holds it securely against the housing of fluid port 15.

The polycarbonate housing has three fastening tabs 17 molded to it that are needed, as discussed above, for clip attachment. A flexible tube connector 58 projects from the side of fluid port 15 and is used to connect chamber 50 with a flexible tube that is not shown. Metal shell 66 forms an annular edge 34 at its distal end that is needed for the holding springs 33 of holding device 13.

Fig. 9 shows a cross-sectional view along line IX-IX in Fig. 8, showing that the crosspieces 19 are closer together than the clip legs 23 of the clips 18. This makes it possible for the projections 42 on the clip pushers 21 to exert a torque on the clip legs 23 that allows the clip legs 23 to be bent.

Fig. 10 shows a cross-sectional view of the distal end of headpiece 12. It can be seen that the clip pushers 21 are located in swallowtail cut-outs in receptacle 14. Receptacle 14 has grooves 37 between the clip pushers 21 to accommodate the holding springs 33.

Headpiece 12 can be screwed off and disposed of after the surgical clip applying instrument has been used, while the rest of the instrument can be reused after sterilization.

Patent claims

1. Surgical clip applying instrument (1) comprising
   - a handle (4) with an actuating device (6),
   - a shaft tube (2) that is attached to said handle (4) and in which a pushrod (28) is located that can be moved axially by the actuating device (6), and
   - a clip device (10) at the distal end of the pushrod (28),

   wherein said clip device (10) has a receptacle (14) for a fluid port (15).

2. The clip applying instrument of claim 1, wherein the clip device (10) is comprised of a headpiece (12) that can be removed from the shaft tube (2).

3. The clip applying instrument of claim 1 or claim 2, wherein the receptacle (14) has a holding device (13) for the fluid port (15).

4. The clip applying instrument of any one of claims 1 to 3, wherein a number of fastening tabs (17) are molded onto the fluid port (15), with the clips (18) of the clip device (10) and the fastening tabs (17) being matched to each other.

5. The clip applying instrument of claim 4, wherein the fastening tabs (17) have crosspieces (19) for bending the clip legs (23) of the clips (18).

6. The clip applying instrument of any one of claims 1 to 5, wherein the clip device (10) has a clip pusher (21) for each clip (18) being attached that pushes the clip (18) forward axially in the distal direction and uses two projections (42) that work together with the crosspieces (19) of the fastening tab (17) to bend the clip legs (23) of the clip (18).

7. The clip applying instrument of any one of claims 1 to 6, wherein the clip device (10) has a plunger (25) that can be moved axially by the pushrod (28).

8. The clip applying instrument of claim 7, wherein an ejector (26) for the fluid port (15) is attached to the plunger (25).

9. The clip applying instrument of claim 7 or claim 8, wherein the plunger (25) exerts pressure against an actuating device for the clip pushers (21) via a compression spring (29) when the pushrod (28) moves distally.

10. The clip applying instrument of claim 9, wherein the compression spring (29) is mounted on a rod part (27) located between the plunger (25) and the ejector (26).

11. The clip applying instrument of claim 9 or claim 10, wherein the actuating device for the clip pushers (21) is comprised of an annular washer (30) that is mounted axially on the rod part (27) extending axially from the plunger (25) and pretensioned by the compression spring (29).

12. The clip applying instrument of claim 11, wherein the annular washer (30), in its pretensioned resting position, bears against a stop (31) formed by the ejector (26).

13. The clip applying instrument of any one of claims 4 to 12, wherein the receptacle (14) for the fluid port (15) accommodates the clips (18) for the fastening tabs (17) and the clip pushers (21).

14. The clip applying instrument of any one of claims 3 to 13, wherein the holding device (13) is comprised of a number of holding springs (33) that engage under an annular edge (34) on the outer circumference of the fluid port (15).

15. The clip applying instrument of any one of claims 2 to 14, wherein the headpiece (12) that can be removed from the shaft tube (2) is comprised of a threaded head (35) and a pipe section (36) connected to the threaded head (35).

16. The clip applying instrument of claim 15, wherein the receptacle (14) for the fluid port (15) is

integrated into the clip device (10) and located at the distal end of the pipe section (36).

17. The clip applying instrument of any one of claims 1 to 10, wherein the pivoting lever part (6) of the handle (4), when in its resting position, is positioned against a stop surface (11), which can be released using a pushbutton (22) so that the lever part (6) can be pivoted far enough to allow the pushrod (28) to be removed from the shaft tube (2) at the proximal end of the handle (4).

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 5

Fig. 6

Fig. 7

Fig. 8

Fig. 9

Fig. 10

INTERNATIONAL SEARCH REPORT

[the next two pages are in English, followed by corresponding German version of the same document.]